

REMARKS

Claims 1, 3-5, 7-8, 13-14 and 21 are pending after entry of the amendments set forth herein; Claims 1, 3-5, 14 and 21 are under consideration. Claims 2, 6, 9-12 and 15-20 are canceled without prejudice. Claims 1, and 3-5 are amended, new Claim 21 is added. Support for the amending language "indomethacin" is found in the specification at, for example, paragraph 9 and throughout the Examples. No new matter is added.

REJECTIONS UNDER §112, ¶2

Claims 1-6, 9-10, 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action rejected Claim 1 as being vague and indefinite, because the clinical status of the 'individual' was not defined. Applicants have amended Claim 1 to claim a method to protect an individual from a loss of neurogenesis capacity resulting from neuroinflammation due to irradiation. The Applicants respectfully maintain that inherent in this description is the definition of the individual as any individual that has been exposed to, or is scheduled to be exposed to irradiation.

The Office Action has also rejected Claim 1, alleging that the term "protecting" of Claim 1 is a relative term which renders the claim indefinite. The Office Action states that the term "protecting" is not defined by the aim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Examiner is not sure whether it means "preventing", "reducing" or "stopping" an individual from a loss of neurogenesis capacity.

Applicants have amended Claim 1 to recite that the method of the invention acts to reduce loss of neurogenesis capacity.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

REJECTIONS UNDER §101

Claims 1-6, 9-10 and 13-15, are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6, 10-11 and 14-16 of co-pending U.S. Application No. 11/473,196. This is a double patenting rejection.

Effective May 29, 2008, Applicants have elected restrictions to the claims of U.S. Application No. 11/473,196 that exclude the claims pending herein, rendering this rejection moot.

REJECTIONS UNDER §102

Claims 1-5 and 14 have been rejected under 35 U.S.C. 102(b) as anticipated by Tada et al. (Neurosurgery 41: 209-219, 1997 – online publication 1-19 pages).

Claims 1, 6, 9, 10, 13 and 14 have been rejected under 35 U.S.C. 102(b) as anticipated by Ferencik et al. (Bratisl Lek Listy 102(3): 123-32, 2001).

Claims 1, 6, 9, 10, 13 and 14 have been rejected under 35 U.S.C. 102(b) as anticipated by Rogers et al. (Neurology 43: 1609-1611, 1993 – included in 1449).

Claims 1, 6, 9, 10, 13, 14 and 15 have been rejected under 35 U.S.C. 102(e) as anticipated by Hensley et al. (US Patent Application Publication NO, 20040014721, filed on 5 June 2003).

Claims 1, 6, 9, 10, 13 and 14 have been rejected under 35 U.S.C. 102(e) as anticipated by Mayer et al. (US Patent No. 6,602,881, filed on 13 May 2002, with a prior filing date of 24 March 2000, US Patent Application No. 09/535,291, Meyer et al).

The Office Action has rejected Claims 1-5 and 14 as anticipated by Tada *et al.* The Office Action states that Tada *et al.* teach the protective effect of the anti-inflammatory agent dexamethasone on radiation-induced brain damage in Japanese primates.

Applicants have amended Claim 1 to specify that the anti-inflammatory agent is a non-steroidal anti-inflammatory drug. Dexamethasone is a *corticosteroidal* drug, and thus outside of the scope of the present claims. Applicants note that paragraph 23 of the specification teaches that “corticosteroids intrinsically inhibit neurogenesis and accentuate the already detrimental effects of neuroinflammation on neurogenesis.”

In view of the above amendments and remarks, withdrawal of the rejection is requested.

The Office Action has rejected Claims 1, 6, 9, 10, 13 and 14 as anticipated by Ferencik *et al.* The Office Action states that Ferencik teach that 1) long term administration of non-steroidal anti-inflammatory drugs (NSAID) in subjects with Alzheimer's Disease and senile dementia result in a protective effect on the onset of AD and slows down the progression of the

disease; and 2) it is a well-established fact that neurodegenerative diseases like AD and dementia are associated with progressive loss of neurogenesis in the central nervous system.

Applicants have canceled Claims 6, 9 and 10, rendering rejection of these claims moot. In addition, the Applicants have amended Claim 1 to specify irradiation as the causative agent of neuroinflammation and the subsequent loss of neurogenesis capacity, and thus provides limitations not found in the cited art.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

The Office Action has rejected Claims 1, 6, 9, 10, 13 and 14 as anticipated by Rogers et al. (Neurology 43: 1609-1611, 1993 – included in 1449). The Office Action states that 1) Rogers demonstrate that the NSAID indomethacin produced a protective effect on the cognitive decline in mild to moderately impaired AF patients, as compared to a placebo control; and 2) it is a well-established fact that neurodegenerative diseases like AD and dementia are associated with progressive loss of neurogenesis in the central nervous system, leading to cognitive impairment. Hence, the Office Action concludes, the invention is anticipated by the teachings of Rogers.

Applicants have canceled Claims 6, 9 and 10, rendering rejection of these claims moot. In addition, the Applicants have amended Claim 1 to specify irradiation as the causative agent of neuroinflammation and the subsequent loss of neurogenesis capacity, and thus provides limitations not found in the cited art.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

The Office Action has rejected Claims 1, 6, 9, 10, 13, 14 and 15 as anticipated by Hensley et al. The Office Action states that Hensley teach 1) the use of the anti-inflammatory compound bis(polyhydroxyphenyl), alone or in combination with NSAIDs, when administered to an individual, slows the progression of neurological diseases resulting from neuroinflammation by the stimulation of microglial cells; and 2) the anti-inflammatory compounds can be used for various neurological disorders of the central nervous system as well as for diseases of the peripheral nervous system.

Applicants have canceled Claims 6, 9 and 10, rendering rejection of these claims moot. In addition, the Applicants have amended Claim 1 to specify irradiation as the causative agent of neuroinflammation and the subsequent loss of neurogenesis capacity, and thus provides limitations not found in the cited art.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

The Office Action has rejected Claims 1, 6, 9, 10, 13 and 14 as anticipated by Mayer *et al.* The Office Action states that Mayer teach the use of the anti-inflammatory compound manzamine, alone or in combination with NSAIDs (such as indomethacin), for the prevention and control of neuroinflammation conditions of the central nervous system involving microglia.

Applicants have canceled Claims 6, 9 and 10, rendering rejection of these claims moot. In addition, the Applicants have amended Claim 1 to specify irradiation as the causative agent of neuroinflammation and the subsequent loss of neurogenesis capacity, and thus provides limitations not found in the cited art.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

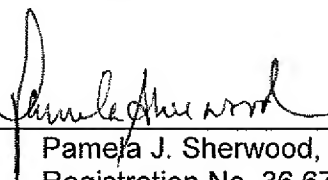
CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-303.

Respectfully submitted,
BOZICEVIC, FIELD &
FRANCIS LLP

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By: 
Pamela J. Sherwood, Ph.D.
Registration No. 36,677

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231